

## **REMARKS**

In the Office Action dated June 22, 2007, the Examiner rejected claims 11 and 13 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter; rejected claim 17 under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, alleged results in an improper definition of a process; rejected claim 17 under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention; rejected claims 1-4 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,662,806 to Keshaviah et al. ("Keshaviah"); rejected claims 1-10, 12, 14, and 16 under 35 U.S.C. § 102 as being anticipated by WO 88/55166 to Sternby ("Sternby"); and rejected claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Sternby in view of U.S. Patent No. 6,284,141 to Shaldon ("Shaldon").

By this Reply, Applicants have canceled claims 11 and 13 and have amended claims 6, 16, and 17. Accordingly, claims 1-10, 12, and 14-17 are currently pending in this application. No new matter has been added by this Reply.

The Examiner rejected claims 11 and 13 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Examiner indicated that the "claims are directed to computer programs, and not an actual encoded apparatus with the claimed program." (Office Action at 2.) Applicants submit that the Examiner's rejection has been rendered moot by the cancellation of claims 11 and 13. Accordingly, Applicants ask that the Examiner withdraw this rejection.

The Examiner also rejected claim 17 under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, alleged results in an improper definition of a process. Applicants submit that the Examiner's

rejection has been rendered moot by Applicants' amendment of claim 17. Accordingly, Applicants ask that the Examiner withdraw this rejection.

The Examiner further rejected claim 17 under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. The Examiner contends that "[c]laim 17 provides for the use of a device capable of performing certain calculations, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass." (Office Action at 3.) Applicants submit that the Examiner's rejection has been rendered moot by Applicants' amendment of claim 17. Accordingly, Applicants ask that the Examiner withdraw the rejection.

Applicants respectfully traverse the Examiner's rejection of claims 1-4 under 35 U.S.C. § 102 as being anticipated by Keshaviah. Applicants submit that Keshaviah does not disclose each and every element of independent claim 1. The Examiner contends that Keshaviah discloses "that the prior art uses a method of determining dialyzer clearance comprising the steps of measuring a blood urea concentration at the end of treatment . . . as well as once a month outside of treatment . . . [and t]he method then uses a ratio between these measurements . . . to derive a clearance ratio that represents the effect on the patient of the dialysis cleaning capacity." (Office Action at 3-4.) Applicants disagree. Keshaviah discloses that a "urea concentration value [from an initial blood sample] then is utilized as the initial hemodialysis treatment value. The final or post hemodialysis treatment value is obtained from a blood sample taken after the end of the hemodialysis treatment. The urea concentration ratio from these two blood samples then is utilized to determine the efficiency of the hemodialysis treatment,

which provides a  $KT/V$  value.” (Col. 10, lines 56-63.) Keshaviah does not, however, disclose a method of estimating a process efficiency comprising the step of “determining a whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) defining a patient’s response to the potential cleaning capacity ( $K_{eff}$ ,  $K$ ),” as recited in claim 1. Keshaviah is silent about determining both a whole body clearance ratio and a potential cleaning capacity, both of which relate to ratios between different clearance values, as recited in claim 1.

Keshaviah merely discloses that an efficiency can be determined as a result of urea concentrations measured from two different blood samples. Thus, claim 1 is allowable over Keshaviah. Accordingly, claims 2-4 are allowable at least due to their dependence from allowable claim 1, and due to their additional recitations of novel subject matter.

Applicants also respectfully traverse the Examiner’s rejection of claims 1-4 under 35 U.S.C. § 102 as being anticipated by Sternby. Applicants submit that Sternby does not disclose each and every element of independent claim 1, 6, and 16. The Examiner contends that Sternby “discloses “that the prior art uses a method of determining dialyzer clearance comprising the steps of measuring a blood urea concentration immediately at the end of treatment . . . as well as 30-60 minutes after treatment, which is interpreted by the examiner to encompass applicant’s claimed ‘no earlier than...one half hour after the end of treatment’ (see p 10).” (Office Action at 4.) Applicants disagree. Applicants concede that Sternby discloses that “the normally used dialyzer clearance is replaced by a whole body clearance  $K$  defined as the ratio between urea mass removal rate and mean urea concentration  $C_m$  in the body. The urea mass removal rate is measured by the urea monitor and is the urea concentration ( $c_d$ ) in the effluent dialysate times the effluent dialysate flow ( $Q_d$ ).” (Page 10, lines 17-23.)

Regarding claim 1, however, Sternby does not disclose a method of estimating a process efficiency comprising the step of “determining a whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) defining a patient’s response to the potential cleaning capacity ( $K_{eff}$ ,  $K$ ),” as recited in claim 1. The whole body clearance disclosed in Sternby, as discussed above, does not disclose a “patients response to the potential cleaning capacity ( $K_{eff}$ ,  $K$ ).” Nor does Sternby disclose determining both a whole body clearance ratio and a potential cleaning capacity, both of which relate to ratios between different clearance values, as recited in claim 1. Thus, claim 1 is allowable over Sternby. Accordingly, claims 2-5 and 12 are allowable at least due to their dependence from allowable claim 1, and due to their additional recitations of novel subject matter.

Regarding claim 6, Sternby does not disclose a “method of estimating a whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to an effective clearance ( $K_{eff}$ )” (emphasis added), as recited in claim 6. Sternby fails to disclose a whole body clearance relating to an effective clearance. Nor does Sternby disclose “determining the whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to the effective clearance ( $K_{eff}$ ), based on a measurement of a slope ( $K_{wb}/V$ ) of a logarithmic removal rate function ( $C_d$ ,  $C_b$ )” (emphasis added), as recited in claim 6. Sternby makes no mention of utilizing a logarithmic removal rate function to determine a whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to the effective clearance ( $K_{eff}$ ). Thus, claim 6 is allowable over Sternby. Accordingly, claims 7-10 and 14 are allowable at least due to their dependence from allowable claim 6, and due to their additional recitations of novel subject matter.

Regarding claim 16, Sternby does not disclose an apparatus comprising “a processor configured to determine the whole body clearance ratio ( $K_{wb}/K_{eff}$ ) for the

patient, the whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to the effective clearance ( $K_{eff}$ ), being determined as the product of said slope ( $K_{wb}/V$ ) and said predialysis urea mass ( $m_0$ ), divided by said flow rate ( $Q_d$ ) and divided by said initial dialysate urea concentration ( $C_{d0}$ )," as recited in claim 16. As discussed above regarding claims 1 and 6, Sternby does not disclose determining a whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to the effective clearance ( $K_{eff}$ ). Thus, claim 16 is allowable over Sternby. Accordingly, claim 17 is allowable at least due to its dependence from allowable claim 16, and due to their additional recitations of novel subject matter.

Applicants respectfully traverse the Examiner's rejection of claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Sternby in view of Shaldon. Applicants submit that the combination of Sternby and Shaldon does not disclose or suggest each and every element of claim 15. The Examiner asserts that Shaldon discloses "the steps of performing dialysis under a first set of conditions and analyzing the set of conditions to determine a particular result, which is affected by the operating parameters of the dialysis procedure . . . [and O]nce the first operation is finished, the method comprises the steps of performing the blood treatment procedure under a second set of conditions if necessary." (Office Action at 5-6.) As discussed above regarding independent claim 1, Sternby does not disclose "a method of estimating a process efficiency comprising the step of "determining a whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) defining a patient's response to the potential cleaning capacity ( $K_{eff}$ ,  $K$ )." And, as discussed above regarding claim 6, Sternby does not disclose a "method of estimating a whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to an effective clearance ( $K_{eff}$ )." Accordingly, Shaldon fails to overcome the above-mentioned deficiencies of Sternby and

independent claims 1 and 6 are allowable over these references. Therefore, claim 15 is allowable over Sternby in view of Shaldon at least due to its dependence from allowable independent claims 1 and 6 and in view of its additional recitation of novel subject matter.


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By:   
Aaron L. Parker  
Reg. No. 50,785